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Edward E. Wallach, M.D., President

December 29, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket #97N-484S
Suitability Determination for Donors of Human Cellular and Tissue-Based Products

Gentlemen:

As a physician and patient care advocate, I welcome any recommendation to improve upon the quality of medicine and the prevention of any harm inflicted to any of our patients. I understand the need for regulation of the donation of human cellular and tissue-based products. Nevertheless, human female gamete (oocytes) and embryos must be considered as entirely separate entities. Quarantining of human embryos should be considered differently, based on the following reasons:

1. There is no evidence of HIV or any other infectious disease passed through IVF or ET during the 21 years of world-wide experience.
2. Quarantining of the embryos will not only increase the costs of Assisted Reproductive Technology, but it will compromise the outcome that is already obtained using fresh embryos for transfer.
3. There will be an unnecessary increase in the number of dead embryos, due to the strain of the freeze/thaw process.
4. There will be an exponential increase in the number of embryos stored and might increase the risk of human error, as well as expose a greater number of embryos to be abandoned or orphaned in the IVF cryopreservation banks.
5. The Society for assisted Reproductive Technology and the Center for Disease Control have worked very closely during the past few years to standardize and regulate the IVF practices, and to establish the regulatory guidelines to assure the optimum care of reproductive medicine.
6. There is no scientific justification to back-up the recommendation of further quarantining at the present time.

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Therefore, we respectfully suggest to the FDA that it take a different approach with regards to quarantining the human cellular and tissue-based products and human gametes and embryos. It is understandable that there should be quarantine for semen samples, but not for a single cell as a human egg or an embryo, since ***there are no leukocyte population with the embryo. Therefore, the risk of transmitting any virus or infectious disease is almost nil.***

Your consideration of an alternative approach would be very much appreciated.

Sincerely yours,

Edward E. Wallach, M. D.
J. Donald Woodruff Professor of Gynecology
Director, Assisted Reproductive Technology Program

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